510(k) Summary
Mercury™ Spinal System

510(k) Number K091587 JUL - 1 2009

Manufacturer Identification

Submitted by: Spinal Elements, Inc.
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010
760-607-0121

Contact Information: Kerri DiMartino
Regulatory Affairs Specialist
Spinal Elements, Inc.
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010
760-607-1816
kdimartino@spinalelements.com

Date Prepared: May 28, 2009

Device Indentification

Proprietary Name	Mercury™ Spinal System
Device Classification	Spinal Interlaminal Fixation and Spinal Intervertebral Fixation Orthosis and/or Pedicle Screw System (per 21 CFR Section 888.3050, 888.3060 and/or 888.3070)
Regulatory Class	Class III
Device Product Code	NKB, MNI, MNH, KWP, KWQ

Device Description

Spinal Elements' Mercury Spinal System is comprised of a variety of screws, rods, and staples that are used for attachment to the non-cervical spine (T1-S1). A variety of constructs may be assembled to suit the individual pathology and anatomy of the patient. Rods span the distance between screws and achieve fixation by the mechanical joining of the rods with the screws. Staples (when used) are placed under the head of the polyaxial or monoaxial screws to help distribute loads placed against the bone.

Screws, rods, and staples are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3.

Intended Use of the Device

The Mercury Spinal System is intended to provide immobilization and stabilization of the spine in skeletally mature patients as an adjunct to fusion for procedures of the thoracic,

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lumbar, and sacral spine (T1-S1). This system is intended for anterior/anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

This system is intended to be used with bone graft.

Substantial Equivalence

The Mercury Spinal System was shown to be substantially equivalent through comparison to the following predicate spinal systems: Mercury Spinal System by Spinal Elements (K071914, K082353, K083230), and XIA Spine Systems by Stryker Spine (K984251).

Performance Data

Mechanical testing indicates that Mercury Spinal System devices are capable of performing in accordance with their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2009

Spinal Elements, Inc.
% Ms. Kerri DiMartino
Regulatory Affairs Specialist
2744 Loker Ave., W. SUITE 100
Carlsbad, CA 92010

Re: K091587
Trade/Device Name: Mercury Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: May 28, 2009
Received: June 2, 2009

Dear Ms. DiMartino,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

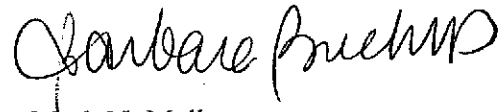
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091587

Device Name: Mercury™ Spinal System

Indications for Use:
The Mercury Spinal System is intended to provide immobilization and stabilization of the spine in skeletally mature patients as an adjunct to fusion for procedures of the thoracic, lumbar, and sacral spine (T1-S1). This system is intended for anterior/anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

This system is intended to be used with bone graft.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(CEXT for MKM)
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091587